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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,758	09/23/2005	Young Ok Kim	58049-00019	1382
7590	10/30/2006			
			EXAMINER	
			RAGHU, GANAPATHIRAM	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/550,758	KIM ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Ganapathirama Raghu	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 August 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 and 5-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 5-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/19/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

Claims 1-3 and 5-20 are pending in this application and are now under consideration for examination.

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-3, 5, 9 13-14 and 20 drawn to an isolated protein of SEQ ID NO: 7 for prosecution in their response dated Aug. 25, 2006 is acknowledged. The traversal is on the grounds that the inventions of Group II drawn to the polynucleotide of SEQ ID NO: 6 encoding the elected polypeptide and Group III comprising the microorganism producing the elected polypeptide, be examined along with Group I, therefore restriction between Groups I, II and III should be withdrawn. Applicants' arguments have been considered favorably as the elected polypeptide, encoding polynucleotide and method of making the polypeptide in a host cell are linked and therefore examiner has joined all the groups and considering them as a single invention. However examiner continues to maintain Kim et al., (Biotechnol. Letters., 2003, Vol. 25: 1231-1234) as prior art due to the fact that the English translation for the Korean application 10-2003-0018573 filed on 03/25/2003 is not provided.

***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a 371 PCT/KR04/00680 filed on 03/25/2004 and claims the priority date of Korean application 10-2003-0018573 filed on 03/25/2003. However, examiner notes that a certified copy of the English translation for the Korean application is not provided.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 19 June 2006 was filed after the mailing date of the application on 09/23/2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Objections***

Claim 7 is objected to, due to the following informality: Claims 7 recites the phrase "base sequence" in the claim. Examiner suggests changing the phrase to "nucleotide sequence", appropriate correction is required.

Claims 8 and 17 objected to because of the following informalities:

Applicant is advised that should claim 8 be found allowable, claim 17 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 6-7 and 15-16 are rejected under 35 U.S.C. 101 because the claims read on non-statutory subject matter. The claim is drawn to 'A gene ...', which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated gene ...' to show the hand of man and in order to overcome the rejection.

Claims 8, 10-11 and 17-19 are rejected under 35 U.S.C. 101 because the claims read on non-statutory subject matter. The claim is drawn to 'A microorganism ...', which could read on product of nature. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated microorganism ...' to show the hand of man and in order to overcome the rejection.

#### *Claim Rejections: 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and claims 2-3 and 5-20 dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although Claim 1 is directed to an isolated protein comprising an amino acid sequence of SEQ ID NO: 2 at its N-terminus and comprising the sequence of SEQ ID NO: 7 with specific biochemical properties and substrate specificity and activity levels, said claim does not clearly state the activity of the of said

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polypeptide. Examiner recommends incorporating the activity of said polypeptide into claim 1. Clarification and correction is required. For purposes of further examination claim 1 is presumed to recite "An isolated protein having phytase activity".

Claim 1 and dependent claims 2-3 and 5-20 dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "... pancreatin.pancreatin". If applicant intended the claim to mean "pancreatin", examiner recommends the claim to be modified to state "pancreatin". Clarification and correction is required.

Claims 2, 3, 5, 7 and claims 14-16, 18-20 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 3, 5, 7 recites the phrase "as set forth in SEQ ID NO: 7 or SEQ ID NO: 6". It is not clear to the examiner whether as to what this phrase means in the context of the above claims, it is not clear whether the isolated protein or nucleic acid indeed actually has the sequence SEQ ID NO: 7 or SEQ ID NO: 6 or whether SEQ ID NO: 7 or SEQ ID NO: 6 is a representative sequence of the isolated protein or polynucleotide. Examiner suggests applicants to make a direct reference to the SEQ ID NO: 7 or SEQ ID NO: 6 such as " a polypeptide sequence of SEQ ID NO: 7 or a polynucleotide sequence of SEQ ID NO: 6".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one of skilled in the relevant art that the invention(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is directed to a genus of nucleic acids encoding a polypeptide having phytase activity and comprising amino acid sequence of SEQ ID NO: 2. The specification does not contain any disclosure of the structure of all nucleic acid sequences included in the claimed genera i.e., polypeptide having phytase activity. The genus of nucleic acids claimed is large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally distinct nucleic acids are encompassed within the scope of the claims. The specification discloses only a single species of claimed genus i. e., a polynucleotide of SEQ ID NO: 6 encoding SEQ ID NO: 7 and having phytase activity, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of DNAs may be achieved by a recitation of structural features common to members of genus, **which features constitute a substantial portion of the genus**. The only recited structural feature of the genus (i.e., a polynucleotide encoding a protein comprising SEQ ID NO: 2) does not constitute a substantial portion of the genus as the remainder of the structure of any nucleic acid encoding a polypeptide having the phytase activity is completely undefined and the specification does not define the remaining structural features

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necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov <http://www.uspto.gov>](http://www.uspto.gov).

Claim 1 and claims 2-3, 5-10 and 12-20 dependent therefrom are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 7 having phytase activity, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus and encoded by a polynucleotide comprising the sequence of SEQ ID NO: 6, or a *Citrobacter braakii* YH-15 strain producing said polypeptide, method of making said polypeptide and a feed additive comprising said polypeptide, does not reasonably provide enablement for any polypeptide comprising an amino acid sequence having at least 70%-99% sequence homology to SEQ ID NO: 7 and having phytase activity, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus and encoded by any polynucleotide having at least 70%-99% sequence homology to SEQ ID NO: 6, or a microorganism belonging to *Citrobacter* species producing said polypeptides, method of making said polypeptides and a feed additive comprising said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-3 and 5-10 and 12-20 are so broad as to encompass any polypeptide comprising an amino acid sequence having at least 70%-99% sequence homology to SEQ ID NO: 7 and having phytase activity, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus and encoded by any polynucleotide having at least 70%-99% sequence homology to SEQ ID NO: 6, or a microorganism belonging to *Citrobacter* species producing said polypeptides, method of making said polypeptides and a feed additive comprising said polypeptides. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and encoding polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 7

having phytase activity, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus and encoded by a polynucleotide comprising the sequence of SEQ ID NO: 6, or a *Citrobacter braakii* YH-15 strain producing said polypeptide, method of making said polypeptide and a feed additive comprising said polypeptide. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides. The specification is limited to teaching the making and using a polynucleotide with SEQ ID NO: 6 encoding for a polypeptide with SEQ D NO: 7 having phytase activity, vector, isolated host cell or a *Citrobacter braakii* YH-15 strain producing said polypeptide and method of making said polypeptide, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to

modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass all modifications and any polypeptide comprising an amino acid sequence having at least 70%-99% sequence homology to SEQ ID NO: 7 and having phytase activity, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus and encoded by any polynucleotide having at least 70%-99% sequence homology to SEQ ID NO: 6, or a microorganism belonging to *Citrobacter* species producing said polypeptides, method of making said polypeptides and a feed additive comprising said polypeptides, because the specification does not establish: (A) regions of the polynucleotide/ protein structure which may be modified without affecting the activity of phytase; (B) the general tolerance of the phytase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue in the polypeptide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides with an enormous number of modifications to the polypeptide of SEQ ID NO: 7 having phytase activity and encoding polynucleotide of SEQ ID NO: 6 and further screening all *Citrobacter* species to isolate a polypeptide with specific characteristics as claimed in claim 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient

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guidance, determination of polypeptides and encoding polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 11 recites a *Citrobacter braakii* YH-15 strain deposited at the Korean Culture Centre of Microorganisms, Hongje-I-dong, Sendaemun-gu, SEOUL 120-091, Republic of Korea and given the following Deposit Accession number: KCCM 10427, Date of Deposit: October 02, 2002.

It is apparent that *Citrobacter braakii* YH-15 strain, Deposit Accession number: KCCM 10427 is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC112, first paragraph, may be satisfied by a deposit of the *Citrobacter braakii* YH-15 strain. The specification does not disclose a repeatable process to obtain the organism and does not show that it is readily available to the public.

It is noted that applicants have deposited the organism but there is no indication in the specification as to the public availability. If a deposit was made under the terms of Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of

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record over his/her signature and registration number, or someone empowered to make such a statement, stating that the invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. The applicant must submit a statement from a person to corroborate the fact, stating that the biological material specifically identified in the application as filed.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make same, or by a statement by an attorney of record over his /her signature and registration number showing that:

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;
- (c) the deposit will be maintained in public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and the deposit will be replaced if it should ever become inviable.

***Claim Rejections 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 5, 8-14 and 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al., (Biotechnol. Letters., 2003, Vol. 25: 1231-1234). Claims 1-3, 5, 8-14 and 17-20 are directed to an isolated polypeptide from *Citrobacter braakii* YH-15 strain, said polypeptide comprising an amino acid sequence having at least 70% sequence homology to SEQ ID NO: 7 and having phytase activity with a specific activity of said polypeptide to phytate is at least 3,000 units/mg, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus, method of making said polypeptide and a feed additive comprising said polypeptide. Kim et al., disclose the isolation and characterization of a phytase polypeptide with exactly the same physico-chemical, biochemical properties and having phytase activity with a specific activity of said polypeptide to phytate is 3,457 units/mg to the protein of the instant invention, comprising the amino acid sequence of SEQ ID NO: 2 at the N-terminus (Abstract section, page 1231; Discussion section, third paragraph, page 1234) and the commercial use of polypeptide with phytase activity as feed additive (Introduction section, second paragraph, page 1231). Said reference is silent regarding the isolated polypeptide comprising the sequence of SEQ ID NO: 7, however examiner takes the position that the source of the reference polypeptide is the same as the instant invention with the same N-terminus sequence (SEQ ID NO: 2) and therefore the reference polypeptide and the polypeptide of the instant invention are one and the same.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the

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protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

As the English translation of the foreign priority documents are not provided with the filing of the PCT application, the filing date of 371 PCT/KR04/00680 filed on 03/25/2004 is the priority date granted for this application.

***Claim Rejections 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over Kim et al., (Biotechnol. Letters., 2003, Vol. 25: 1231-1234). Claim 6 is directed to an isolated polynucleotide encoding a

polypeptide from *Citrobacter braakii* YH-15 strain, said polypeptide having phytase activity with a specific activity of said polypeptide to phytate is at least 3,000 units/mg, said polypeptide further comprising the sequence of SEQ ID NO: 2 at its N-terminus. The many advantages of recombinant production of useful proteins are well known within the art as are recombinant methods of obtaining the necessary genes. These advantages include the ability to produce much larger quantities of the protein, being able to produce the protein in more easily handled organisms, reducing the number of steps necessary for the purification of a protein and producing the protein in a purer form by using an organism that does not include naturally occurring contaminants of the protein. As such the disclosure of a useful protein and the N-terminus sequence of said polypeptide comprising the sequence of SEQ ID NO: 2 such as that of Kim et al., enables one to synthesize oligonucleotide probes for screening genomic or cDNA expression libraries and clearly suggests to the ordinary skilled artisan, a gene encoding for the protein as such a gene would be useful to produce large quantities of the protein. Therefore, it would have been obvious to one of ordinary skill in the art to isolate and express the gene encoding the phytase of *Citrobacter* disclosed by Kim et al. using well known recombinant methods for the isolation of such genes, insertion of the isolated gene into an expression vector, transformation into a suitable host and expression of the encoded protein.

### ***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533.

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The examiner can normally be reached on 8 am - 4.30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

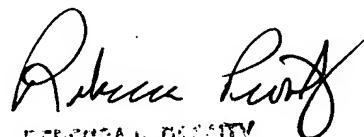
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.

Patent Examiner

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Oct. 06, 2006.



REBECCA E. PACUTY  
PRIMARY EXAMINER  
GROUP 1600  
1652